EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	)	
Plaintiffs/Counterclaim-Defendants,	)	Civ. Action No. 05-371 (KAJ)
v.	)	
MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES INC.,	)	
Defendants/Counterclaim-Plaintiffs.	)	

DEFENDANTS' OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF REQUESTS FOR DOCUMENTS AND THINGS (Nos. 1-35)

Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan"), pursuant to Federal Rules of Civil Procedure 26 and 34, hereby submit their Objections and Responses to the First Set of Requests for Documents and Things (Nos. 1-35) of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Janssen"). These Objections and Responses are based on information and documents presently available as a result of a search and review process that is continuing. Mylan reserves the right to supplement and/or amend its responses as necessary or appropriate.

OBJECTIONS APPLICABLE TO ALL DOCUMENT REQUESTS

Each of these objections is applicable to each of Janssen's Requests and is incorporated into each and every one of Mylan's responses to Janssen's Requests as though fully set forth therein, and is in addition to any specific objections stated for a particular document request.

1. Mylan objects to Janssen's Requests on the grounds that certain Requests seek documents protected by the attorney-client privilege, the attorney work product doctrine, and/or

other applicable privileges. Consistent with Federal Rule of Civil Procedure 26(b)(5), Mylan will identify the documents created prior to June 7, 2005, for which it asserts a claim of privilege.

2. Mylan objects to Janssen's Requests to the extent that they purport to impose obligations beyond those imposed by the Federal Rules of Civil Procedure and/or the Local Civil Rules of this Court.

3. Mylan objects to Janssen's Requests to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues. *See* FED. R. CIV. P. 26(b)(2)(iii).

4. Mylan objects to Janssen's definitions and instructions to the extent that they (i) change the common meaning of the English language with regard to any word or phrase; (ii) alter the scope of discovery, and purport to impose obligations beyond those imposed, under the Federal Rules of Civil Procedure and/or the Local Civil Rules of this Court; and/or (iii) define terms differently than such terms are defined under the Federal Rules of Civil Procedure and/or the common law. Mylan also objects to the definition that Janssen has provided for terms used in these requests to the extent that they are overly broad, argumentative, prejudicial, improper, incorrect, vague and/or ambiguous. Specific explanations of the objections will be provided.

5. Mylan objects to Janssen's definition of "you," "your," or "Mylan" as overly broad and unduly burdensome. For purposes of these Requests, "you," "your," or "Mylan" solely shall refer to Mylan Pharmaceutical Inc. and Mylan Laboratories Inc., named Plaintiffs to this litigation.

6. Mylan objects to Janssen's definition of "Patent-in-Suit" as overly broad and not reasonably calculated to lead to the discovery of admissible evidence. Unless otherwise stated, for purposes of Mylan's discovery responses, "Patent-in-Suit" shall solely refer to U.S. Patent No. 4,663,318, issued on May 5, 1987, and *not* to "any foreign counterpart" of that patent.

7. Mylan objects to Janssen's definitions of "document" and "relate to, relates to, refer to or concerning" as unduly burdensome, overly broad, vague, and ambiguous.

8. Mylan objects to Janssen's definition of "Dementia of the Alzheimer's type" as seeking information irrelevant to the issues in this litigation as they relate to Mylan, as this term is outside the scope of the claims of U.S. Patent No. 4,663,318.

9. Mylan objects to Janssen's Requests to the extent that they seek to impose an obligation on Mylan to locate, obtain, and produce documents and things that are in the public domain and, therefore, are equally accessible to Janssen.

10. Mylan objects to Janssen's Requests to the extent that they call for a legal conclusion.

11. Mylan objects to Janssen's Requests to the extent that they seek the production of any documents and things relating to Janssen's improper willful infringement claim. Discovery related to that issue is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence because, among other things, willful infringement is not a proper claim in this litigation. *See Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). Such Requests are therefore premature, presently irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Dismissal or bifurcation of Janssen's willful infringement claims is called for by controlling Federal Circuit case law. Mylan reserves the

right to raise all other objections to such Requests if and when a substantive response is required in accordance with the Federal Rules.

12. Mylan objects to Janssen's Requests as premature in that they seek documents, things and/or information before (i) Janssen has identified which claims of the '318 patent it is asserting and its proposed claim construction of the asserted claims in the '318 patent; and (ii) Mylan has had an opportunity to conduct meaningful discovery.

13. Mylan objects to Janssen's Requests as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence to the extent that they seek documents and things relating to galantamine and/or galantamine products unrelated to Mylan's proposed generic galantamine products under abbreviated new drug application ("ANDA") No. 77-590. Identifying, locating, and producing such documents would be unduly burdensome on Mylan.

14. Mylan's responses to these Requests do not constitute acquiescence or agreement to any definition proposed by Janssen.

15. Mylan's Responses to make available requested documents do not constitute representations that any such documents exist or are in Mylan's possession, custody, or control.

16. To the extent that Janssen's Requests seek documents that embody, contain or refer to confidential and/or proprietary business information or trade secrets, Mylan produces such documents pursuant to Local Rule 26.2, until such time as the Court enters a Protective Order. At that point, the terms of the Protective Order shall govern Mylan's production of such documents.

SPECIFIC OBJECTIONS AND RESPONSES TO PRODUCTION REQUESTS

Production Request No. 1.

All documents that relate to your responses or to which you refer in responding to Plaintiffs' interrogatories.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. "All" documents that relate to Mylan's interrogatory responses are not relevant to the only issues relevant to this case: infringement and invalidity of the '318 patent. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Mylan initially provided a copy of relevant portions of its ANDA to Janssen in May 2005. Mylan produced a full copy of its ANDA (MYLAN(GAL) 00276-02412) on or about October 10, 2005. Mylan further directs Janssen to the documents that Mylan produced in connection with its Rule 26(a)(1) Initial Disclosures on or about September 15, 2005 (MYLAN(GAL) 00001-00275), which relate to the issues of alleged infringement of and/or the validity of the patent-in-suit. Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 2.

All documents referenced in your Initial Disclosures produced in accordance with Fed. R. Civ. P. 26(a)(1).

RESPONSE: Without waiving its general objections, and subject to them, in response to this Request, Mylan states that it has produced all documents in its possession that are referenced in its Rule 26(a)(1) Initial Disclosures, served on Janssen on or about September 12, 2005. Answering further, Mylan states that Janssen has failed to provide its Rule 26(a)(1) disclosures to Mylan and has yet to produce any discovery in this litigation.

Production Request No. 3.

All documents relating to any ANDA (including without limitation Mylan's Abbreviated New Drug Application ("ANDA") No. 77-590), and any amendment, supplemental filing, or addition thereto, submitted by your or on your behalf to the FDA seeking permission to manufacture, market, or sell a drug product containing galantamine or any salt thereof, including without limitation:

a. documents relating to the history and status of any application for approval by FDA of a drug product containing galantamine or any salt thereof, including without limitation any ANDA filed by or for Mylan for such a product and all documents related thereto, including ANDA amendments, supplements, deficiency letters, tentative approval letters, and final approval letters;

b. documents relating to any communication, correspondence, or contact with the FDA by you concerning each such ANDA, and any amendment, supplemental filing, or addition thereto, including but not limited to letters, emails, teleconference minutes, notes, and meeting minutes from discussions held with and between you and the FDA;

c. documents relating to the prosecution of each such ANDA, including but not limited to internal meeting minutes, notes, internal correspondence, draft submissions, and plans;

d. documents relating to the decision to file, the steps taken to prepare, and the timing of the submission of each such ANDA or any of the documents or information contained therein;

e. documents relating to any difficulties, problems, or delays in obtaining FDA approval for any such ANDA; and

f. a complete copy of the Drug Master File referenced in each such ANDA.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning "any" ANDA, amendment, supplemental filing, or addition thereto, as well as a copy of the Drug Master File ("DMF") reference in "any such ANDA." The only products at issue in this case are those found in Mylan's ANDA No. 77-590, as Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents concerning other galantamine products or documents beyond Mylan's ANDA is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim. Mylan also objects to the extent that this Request seeks documents or information that is not in Mylan's possession, custody or control, including the DMF referenced in Mylan's ANDA.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 4.

All documents relating to research and development of any drug product containing galantamine or any salt thereof, including but not limited to laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and

agreements with third parties concerning research and development of drug products containing galantamine or any salt thereof.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning "any drug product containing galantamine." Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents concerning other galantamine products is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 5.

All documents relating to research, analysis, or evaluation for any purpose of a drug product containing galantamine or any salt thereof, including without limitation laboratory notebooks, invention disclosure forms, research, plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and agreements with third parties concerning your research, analysis of evaluation.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning "any drug product containing galantamine." Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents concerning other galantamine products is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 6.

All documents relating to the market or potential market for drug products containing galantamine or any salt thereof, including but not limited to Mylan's proposed galantamine hydrobromide products. Such documents include marketing analyses, business plans, sales projections, market research or surveys, and sales information relating to current galantamine hydrobromide products.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any galantamine drug product, as well as documents unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning the market of any drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim. Mylan further objects to the extent that this Request seeks documents or information that is not in Mylan's possession, custody or control, but rather already in Janssen's possession.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 7.

All documents relating to Mylan's decision to make and sell a drug product containing galantamine or any salt thereof.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any galantamine drug product, as well as documents unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning the decision to make or sell any galantamine drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan also objects to the extent that this Request is duplicative of other Requests, including Request No. 6. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 8.

All documents that relate to any application filed with any governmental agency or regulatory body, whether foreign or domestic, seeking approval to manufacture, market or test a drug product containing galantamine or any salt thereof.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example this Request calls for documents, things, or information concerning "any" application filed with "any" governmental agency or regulatory body concerning any galantamine drug product. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning filings related to any galantamine drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 9.

All documents relating to the types of conditions or indications for which physicians may prescribe a drug product containing galantamine or any salt thereof, and the factors that might influence a physician's decision with respect to whether to prescribe one of these products or any other product for any such condition, including the role of efficacy, side effects, price, brand name, and patents.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents,

things, or information concerning any galantamine drug product. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning types of conditions or indications for which physicians may prescribe a drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Additionally, Mylan objects to the extent any documents sought under this Request are in Janssen's possession. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 10.

All documents relating to research and development of any drug product intended to treat dementia of the Alzheimer's type, including but not limited to laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and agreements with third parties concerning research and development of drug products intended to treat dementia of the Alzheimer's type.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any drug product intended to treat dementia of the Alzheimer's type. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents concerning other galantamine products is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan also objects to the extent that this Request is cumulative or duplicative of Request No. 4. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 11.

All documents relating to research, analysis, or evaluation for any purpose of a drug product intended to treat dementia of the Alzheimer's type, including without limitation laboratory notebooks, invention disclosure forms, research plans, summaries or proposals, compilations of data or data summaries, research protocols, presentations or status reports, meeting minutes, scientific publications, and agreements with third parties concerning your research, analysis or evaluation.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to

lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any drug product intended to treat dementia of the Alzheimer's type, as well as documents and things relating to products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents concerning other galantamine products is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan also objects to the extent that this Request is cumulative or duplicative of Request No. 5. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 12.

All documents relating to the market or potential market for drug products intended to treat dementia of the Alzheimer's type. Such documents include marketing analyses, business plans, sales projections, market research or surveys, and sales information relating to current drug products intended to treat dementia of the Alzheimer's type.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any drug product intended to treat dementia of the Alzheimer's type, as well as documents and things relating to products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning the market of any drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Additionally, Mylan objects to the extent that this Request is cumulative and duplicative of Request No. 6. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim. Mylan further objects to the extent that this Request seeks documents or information that is not in Mylan's possession, custody or control, but already in Janssen's possession.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 13.

All documents relating to Mylan's decision to make and sell a drug product intended to treat dementia of the Alzheimer's type.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any drug product intended to treat dementia of the Alzheimer's type. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning the decision to make or sell any drug product intended to treat dementia of the Alzheimer's type is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan also objects to the extent that this Request is duplicative of other Requests, including Request No. 7. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 14.

All documents that relate to any application filed with any governmental agency or regulatory body, whether foreign or domestic, seeking approval to manufacture, market or test a drug product intended to treat dementia of the Alzheimer's type.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning "any" application filed with "any" governmental agency or regulatory body concerning any drug product intended to treat dementia of the Alzheimer's type. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning filings related to any galantamine drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to the extent that this Request is cumulative and duplicative of other Requests, including Request No. 8. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 15.

All documents relating to the types of conditions or indications for which physicians may prescribe a drug product approved for the treatment of dementia of the Alzheimer's type, and the factors that might influence a physician's decision with respect to whether to prescribe one of these products or any other product for any such condition, including the role of efficacy, side effects, price, brand name, and patents.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any drug product approved for the treatment of dementia of the Alzheimer's type, as well as documents and things relating to products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning types of conditions or indications for which physicians may prescribe a drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to the extent that this Request is cumulative and duplicative of Request No. 9. Additionally, Mylan objects to the extent any documents sought under this Request are in Janssen's possession. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent

based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 16.

All documents relating to Mylan's April 27, 2005 Notice of Paragraph IV Certification to Janssen Pharmaceutica N.V., Janssen Pharmaceutica Products, L.P., and Synaptech, Inc. (hereinafter "Mylan's Paragraph IV Certification").

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Not "all" documents "relating to" Mylan's notice letter are relevant to the only relevant issues in this litigation: infringement and invalidity. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Mylan further directs Janssen to the documents that Mylan produced in connection with its Rule 26(a)(1) Initial Disclosures on or about September 15, 2005 (MYLAN(GAL) 00001-00275), which relate to the issues of alleged infringement of and/or the validity of the patent-in-suit. Moreover, Mylan objects to the extent Janssen already is in possession of Mylan's Notice of Paragraph IV Certification, dated April 27, 2005. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's

ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 17.

All documents relating to the analysis or evaluation for any purpose of any drug product containing galantamine or any salt thereof, including but not limited to Janssen's RAZADYNE®/REMINYL® products.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request calls for documents, things, or information concerning any galantamine drug product and an analysis or evaluation for any purpose. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning an analysis or evaluation of any galantamine drug product is overly broad and unduly burdensome as it relates to the issue of infringement. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 18.

All documents relating Mylan's contention that Plaintiffs have not accurately characterized or described the labeling of proposed galantamine hydrobromide tablets and REMINYL® and RAZADYNE® tablets. (Mylan's Answers, ¶¶ 23, 24).

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Not "all" documents relating to paragraphs 23 and 24 of Mylan's answer are relevant to the issues of infringement and invalidity of the '318 patent. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Mylan further objects to the extent that this Request seeks documents or things already in the possession of Janssen.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 19.

Documents, including corporate organizational charts and/or handbooks sufficient to show Mylan's management structure from one year prior to the decision to develop and sell a drug product containing galantamine or any salt thereof to the present.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. This Request seeks documents of an unlimited scope concerning Mylan's management structure. Documents regarding the management

structure of Mylan are irrelevant to the relevant issues in this case: infringement and invalidity of the '318 patent. Mylan further objects to the extent that this Request seeks documents and things relating to galantamine and/or galantamine products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning the sale of any drug product containing galantamine is overly broad and unduly burdensome as it relates to the issue of infringement.

Without waiving its objections, and subject to them, Mylan will produce current organizational charts, to the extent such documents exist.

Production Request No. 20.

All documents relating to the '318 patent, including without limitation:

a. any evaluation, analysis, or discussion relating to the '318 patent;

b. any communications between Mylan and any third party concerning the '318 patent.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan objects to this Request on the grounds that it is overly broad, unduly burdensome, vague, ambiguous and unlimited in time and/or scope. This Requests seeks "all" documents relating to the '318 patent, with no limitation whatsoever to time or scope. Many categories of documents that concern, refer to, or relate to the '318 patent are

irrelevant to the issues in this case, which include the alleged infringement of the '318 patent, and identifying and locating all such documents would be unduly expensive and time consuming. Additionally, Mylan objects to the extent Janssen is in possession of any documents sought under this Request. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 21.

All documents relating to any patent or patent application filed by or for Mylan or assigned to Mylan describing or claiming a drug product containing galantamine or any salt thereof.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan objects to this Request on the grounds that it is overly broad, unduly burdensome, vague, ambiguous and unlimited as to time and/or scope. Mylan further objects to the extent that this Request seeks documents and things relating to galantamine and/or galantamine products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo,*

Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning any patent or patent application for any galantamine drug product is overly broad and unduly burdensome because it seeks documents that are not relevant to the claim of infringement against Mylan as alleged by Janssen. Mylan further objects to the extent that this Request is duplicative of other Requests, including Request Nos. 8 and 14. Mylan also objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Production Request No. 22.

All documents relating to any patent or patent application filed by or for Mylan or assigned to Mylan describing or claiming any treatment for dementia of the Alzheimer's type, including without limitation any drug product intended for the treatment of dementia of the Alzheimer's type.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan objects to this Request on the grounds that it is overly broad, unduly burdensome, vague, ambiguous and unlimited as to time and/or scope. Mylan further objects to the extent that this Request seeks documents and things relating to galantamine and/or galantamine products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Therefore, a request for documents comprising or concerning any patent or patent application for any galantamine drug product is

overly broad because it seeks documents that are not relevant to the claim of infringement against Mylan as alleged by Janssen. Mylan further objects to the extent that this Request is duplicative of other Requests, including Request Nos. 8, 14 and 21. Mylan also objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Production Request No. 23.

All documents relating to anything that Mylan contends is "prior art" to the '318 patent.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. For example, this Request is not limited to documents that Mylan believes are relevant prior art to the '318 patent. Each and every article published any where in the world more than one year before the priority date of the '318 patent is "prior art" to that patent, but Mylan has not asserted that "all" such articles are relevant and producing all such articles would be unduly burdensome. Mylan further objects to this Request as premature, as Janssen, despite repeated requests, refuses to specify which claims of the '318 patent allegedly are infringed by the products that are the subject of Mylan's ANDA, or would be infringed by the manufacture, use, sale, offer for sale or importation of the products that are the subject of Mylan's ANDA, and to provide, among other things, its proposed claim construction of the asserted claims in the '318 patent. Janssen has failed to identify these claims despite having access to relevant portions of Mylan's ANDA since May 2005. Until such time as Janssen identifies which claims of the '318 patent that it is asserting and what those claims mean, this Request is premature. Mylan also objects to this Request as premature because discovery in this matter only has recently begun, and Mylan has not received any documents or

written discovery from Janssen. Mylan also objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Once Janssen identifies which claims of the '318 patent that it is asserting and provides its construction of these claims, Mylan will supplement its response to this Request with respect to the '318 patent. Mylan further reserves its rights to rely on other prior art references identified by any other defendant in any of the related actions filed by Janssen in connection with galantamine hydrobromide in support of its invalidity claims.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 24.

All documents relating to Mylan's contention that the '318 patent is invalid.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Mylan further objects to this Request as premature, as Janssen, despite repeated requests, refuses to specify which claims of the '318 patent allegedly are infringed by the products that are the subject of Mylan's ANDA, or would be infringed by the manufacture, use, sale, offer for sale or importation of the products that are the subject of Mylan's ANDA, and to provide, among other things, its proposed claim construction of the asserted claims in the '318 patent. Janssen has failed to identify these claims despite having access to relevant portions of Mylan's ANDA since May 2005. Until such time as Janssen

identifies which claims of the '318 patent that it is asserting and what those claims mean, this Request is premature. Mylan also objects to this Request as premature because discovery in this matter only has recently begun, and Mylan has not received any documents or written discovery from Janssen. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Once Janssen identifies which claims of the '318 patent that it is asserting and provides its construction of these claims, Mylan will supplement its response to this Request with respect to the '318 patent. Mylan further objects to the extent that this Request is duplicative of other Requests, including Request Nos. 20 and 23. Mylan further reserves its rights to rely on other prior art references identified by any other defendant in any of the related actions filed by Janssen in connection with galantamine hydrobromide in support of its invalidity claims.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 25.

All documents relating to Mylan's contention that Mylan's proposed galantamine hydrobromide products do not infringe Janssen's RAZADYNE®/REMINYL® products.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Many categories of documents that concern, refer to, or relate to Mylan's ANDA products are irrelevant to the issues in this case, which include

the alleged infringement of the patent-in-suit by the products that are the subject of Mylan's ANDA and the validity/invalidity of the patent-in-suit, and identifying and locating such documents would be unduly expensive and time consuming. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590 (MYLAN(GAL) 00276-02412). *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Mylan further objects to this Request as premature, as Janssen, despite repeated requests, refuses to specify which claims of the '318 patent allegedly are infringed by the products that are the subject of Mylan's ANDA, or would be infringed by the manufacture, use, sale, offer for sale or importation of the products that are the subject of Mylan's ANDA, and to provide, among other things, its proposed claim construction of the asserted claims in the '318 patent. Janssen has failed to identify these claims despite having access to relevant portions of Mylan's ANDA since May 2005. Once Janssen identifies which claims of the '318 patent that it is asserting and provides its construction of these claims, Mylan will supplement its response to this Request with respect to the '318 patent.

Mylan also objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim. Mylan further objects to the extent that this Request is duplicative of other Requests, including Request No. 20.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's

ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 26.

All documents relating to Mylan's third affirmative defense that the United States District Court for the District of Delaware lacks personal jurisdiction over Mylan Laboratories.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the '318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 27.

All documents relating to Mylan Laboratories' contacts with or presence in the State of Delaware.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the

'318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 28.

Documents sufficient to show, on a monthly basis, sales of drug products manufactured or sold by Mylan in the State of Delaware, including the number of units sold, price (including any credits, discounts, and rebates), revenues, costs (including, but not limited to, development, labor, material, ingredient, distribution, manufacturing, marketing, and advertising costs) and profits net of all costs and taxes.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the '318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 29.

Documents sufficient to show all past and current customers of drug products manufactured or sold by Mylan in the State of Delaware including without limitation:

a. the identity of each customer;

b. the date of each sale;

c. the package size, dosage form, and quantities purchased by each customer;

d. the per unit price charged to each customer;

e. all credits, discounts, rebates, or other concessions to the price in connection with the sale of these products to each customer;

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the '318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 30.

All documents relating to contracts, agreements, or arrangements with any customer in the State of Delaware relating to the sale of drug products manufactured or sold by Mylan, including but not limited to offers or solicitations for sale, quotes, orders, and documents sufficient to show any credits, discounts, rebates, or other concessions in connection with the sale of such products.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the '318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 31.

All documents relating to Mylan's fourth defense that Mylan Laboratories is not a proper party to this action.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Mylan Pharmaceuticals is the party that filed the ANDA at issue here. While Mylan does not believe that Mylan Laboratories Inc. is a proper party to this action, Mylan Laboratories has filed an Answer in this litigation. (*See* D.I. 12). Thus, documents relating to whether the Court lacks personal jurisdiction over Mylan Laboratories are irrelevant to the issues in this case, which are the alleged infringement of the '318 patent by the products that are the subject of Mylan's ANDA and the invalidity of the '318 patent, and would be unduly burdensome to identify, locate, and produce.

Production Request No. 32.

All documents relating to Mylan's fifth defense that the Complaint fails to state a claim upon which relief can be granted.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the ground that it calls for a legal conclusion. Federal case law is clear that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). District courts, including in this District, uniformly have applied *Glaxo* to strike or dismiss willful infringement claims based solely on the filing of an ANDA and/or paragraph IV certification. *See Allergan, Inc. v. Alcon, Inc.*, No. 04-0968 (D. Del. July 26, 2005) (striking plaintiff's willful infringement claim) (Sleet, J.); *Aventis Pharma Deutschland GmbH v. Cobalt Pharm.*, 355 F. Supp. 2d 586 (D. Mass. 2005) (granting Rule 12(c) motion for judgment on the

pleadings dismissing claim for willful infringement in ANDA case); *Ortho-McNeil Pharm. v. Mylan Labs.*, No. 04-1689 (D.N.J. Apr. 18, 2005) (same).

Production Request No. 33.

All documents relating to Mylan's sixth defense that the Plaintiff's willful infringement claims fails to state a claim upon which relief can be granted.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the ground that it calls for a legal conclusion. Federal case law is clear that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1350-51 (Fed. Cir. 2004). District courts, including in this District, uniformly have applied *Glaxo* to strike or dismiss willful infringement claims based solely on the filing of an ANDA and/or paragraph IV certification. *See Allergan, Inc. v. Alcon, Inc.*, No. 04-0968 (D. Del. July 26, 2005) (striking plaintiff's willful infringement claim) (Sleet, J.); *Aventis Pharma Deutschland GmbH v. Cobalt Pharm.*, 355 F. Supp. 2d 586 (D. Mass. 2005) (granting Rule 12(c) motion for judgment on the pleadings dismissing claim for willful infringement in ANDA case); *Ortho-McNeil Pharm. v. Mylan Labs.*, No. 04-1689 (D.N.J. Apr. 18, 2005) (same).

Production Request No. 34.

To the extent not otherwise encompassed by other document requests, produce all documents relating to Mylan's affirmative defenses and counterclaims in this case.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. The only information that is relevant to Janssen's infringement allegations is found in Mylan's ANDA No. 77-590. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997). Mylan produced a copy of its ANDA (MYLAN(GAL) 00276-

02412) on or about October 10, 2005. Mylan also directs Janssen to the other documents that Mylan produced in connection with its Rule 26(a)(1) Initial Disclosures on or about September 15, 2005 (MYLAN(GAL) 00001-00275), which relate to the issues of alleged infringement of and/or the validity of the patent-in-suit. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Production Request No. 35.

All documents relating to document retention or destruction at Mylan from one year prior to the decision to develop and sell a galantamine hydrobromide product to the present.

RESPONSE: Mylan, in addition to its general objections, objects to this Request on the grounds that it seeks discovery that is overly broad, irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. This Request seeks documents regarding Mylan's document retention policies. Documents regarding Mylan's document retention policies are irrelevant to the only issues relevant to this case: infringement and invalidity of the '318 patent. Mylan further objects to the extent that this Request seeks documents and things relating to galantamine and/or galantamine products unrelated to Mylan's proposed galantamine products under Mylan's ANDA No. 77-590. Janssen's Complaint only alleges infringement of the '318 patent by Mylan based on Mylan's ANDA products. Therefore, a request for documents

comprising or concerning the sale of any galantamine hydrobromide drug product is overly broad because it seeks documents that are not relevant to the claim of infringement against Mylan as alleged by Janssen. Mylan further objects to this Request to the extent that it seeks documents protected by the attorney-client privilege, the attorney work product doctrine and/or other applicable privileges, and/or documents relating to Plaintiffs' improper willfulness claim.

Without waiving its objections, and subject to them, Mylan will produce all responsive, non-privileged documents relevant to the issues of infringement of the '318 method-of-use patent based upon the manufacture, use, sale, or offer for sale of the products at issue in Mylan's ANDA No. 77-590 and the validity of the '318 patent, to the extent such documents exist and have not already been produced.

Dated: October 10, 2005.

MYLAN PHARMACEUTICALS INC. and
MYLAN LABORATORIES INC.

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of October, 2005, the foregoing document, **DEENDANTS' OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF REQUESTS FOR DOCUMENTS AND THINGS (Nos. 1-35)**, was served by FedEx® and e-mail on the following:

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